



Appendix A

Claim Amendments

1. - 10. (Canceled)

11. (Currently amended) An oral solid active compound unit comprising a microsphere, the microsphere comprising:

a matrix comprising a mixture of at least one fatty alcohol and at least one solid paraffin; and

an acid-labile active compound, wherein the acid-labile active compound in the active compound unit is selected from the group consisting of an acid-labile proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, and a hydrate of a salt of an acid-labile proton pump inhibitor with a base, wherein said acid-labile active compound is present in said matrix, and is present in a matrix made of a mixture comprising at least one fatty alcohol and at least one solid paraffin, wherein said active compound unit is a microsphere.

12. (Currently amended) An oral solid active compound unit comprising a microsphere, the microsphere comprising:

a matrix comprising a mixture of at least one fatty acid ester or at least one triglyceride, and at least one solid paraffin; and

an acid-labile active compound, ~~wherein the acid labile active compound in the active compound unit is~~ selected from the group consisting of an acid-labile proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, and a hydrate of a salt of an acid-labile proton pump inhibitor with a base, wherein said acid-labile active compound is present in said matrix, ~~and is present in a matrix made of a mixture comprising at least one fatty alcohol and at least one solid paraffin, wherein said active compound unit is a microsphere.~~

13. (Currently amended) The oral solid active compound unit as claimed in claim 11, wherein the matrix further comprises one or more excipients selected from the group consisting of polymers, sterols and basic compounds, ~~is/are present in the matrix.~~

14. (Currently amended) The oral solid active compound unit as claimed in claim 11, wherein the active compound present is an acid-labile proton pump inhibitor.

15. (Currently amended) The oral solid active compound unit as claimed in claim 11, wherein the microsphere has a particle size range of 50-800  $\mu\text{m}$ .

16-17. (Canceled)

18. (Currently amended) A process for the production of an oral solid active compound unit in the form of a microsphere comprising an acid-labile active compound, where the acid-labile active compound is selected from the group consisting of an acid-labile proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, and a hydrate of a salt of an acid-labile proton pump inhibitor with a base, and is present in the microsphere in a matrix made of a mixture comprising at least one fatty alcohol and at least one solid paraffin, at least one triglyceride and at least one solid paraffin or at least one fatty acid ester with at least one solid paraffin, comprising the following steps:

a. preparing a solution or dispersion of the acid-labile active compound in the fatty alcohol and paraffin, triglyceride and paraffin or fatty acid ester and paraffin;

b. prilling the solution or dispersion prepared in step (a) and obtaining drops of the solution or dispersion; and

c. solidifying the drops obtained in step (b) in a suitable medium.

19. (Previously presented) The process as claimed in claim 18, where the prilling is carried out by means of vibrating

nozzles, wherein the solution or dispersion which flows to the nozzle is kept at a constant temperature, and wherein the solidification of the drops takes place in a suitable cooling medium after stabilization thereof by sudden quenching.

20. (Currently amended) An oral solid microsphere prepared by the process as claimed in claim 18.

21. - 32. (Canceled)

33. (Currently amended) The oral solid active compound unit as claimed in claim 11, wherein the acid-labile proton pump inhibitor is selected from the group consisting of omeprazole, pantoprazole, lansoprazole and rabeprazole.

34. (Currently amended) The oral solid active compound unit as claimed in claim 11, wherein the acid-labile proton pump inhibitor is pantoprazole sodium sesquihydrate, (-)-pantoprazole sodium sesquihydrate, omeprazole magnesium, omeprazole, esomeprazole magnesium or esomeprazole.

35. (Currently amended) The oral solid active compound unit as claimed in claim 11, wherein the acid-labile proton pump inhibitor is pure enantiomer.

36. (Currently amended) The oral solid active compound unit as claimed in claim 11, wherein the acid-labile proton pump inhibitor is esomeprazole or (-)-pantoprazole.

37. (Currently amended) The oral solid active compound unit as claimed in claim 15, wherein the microsphere has a particle size range of 50-500  $\mu\text{m}$ .

38. (Currently amended) The oral solid active compound unit as claimed in claim 15, wherein the microsphere has a particle size range of 50-400  $\mu\text{m}$ .

39. (Currently amended) The oral solid active compound unit as claimed in claim 38, wherein the microsphere is a monomodal microsphere.

40. (Currently amended) The oral solid active compound unit as claimed in claim 38, wherein the microsphere has a particle size range of 50-200  $\mu\text{m}$ .

41. (Currently amended) The oral solid active compound unit as claimed in claim 11, wherein the fatty alcohol is selected from the group consisting of cetyl alcohol, myristyl

alcohol, lauryl alcohol, stearyl alcohol and mixtures thereof.

42. (Currently amended) The oral solid active compound unit as claimed in claim 12, wherein the triglyceride is selected from the group consisting of tristearate, tripalmitate, trimyristate and mixtures thereof.

43. (Currently amended) The oral solid active compound unit as claimed in claim 12, wherein the fatty acid ester is cetyl palmitate.

44. (Currently amended) The oral solid active compound unit as claimed in claim 11, wherein the solid paraffin is paraffinum solidum or ozocerite.

45-47. (Canceled)

48. (New) The oral solid active compound unit as claimed in claim 11, wherein the microsphere does not comprise an enteric coating.

49. (New) The oral solid active compound unit as claimed in claim 12, wherein the microsphere does not comprise an enteric coating.

50. (New) The oral solid active compound unit as claimed in claim 11, wherein the acid-labile active compound is 1-90% by weight of the oral solid active compound unit.

51. (New) The oral solid active compound unit as claimed in claim 50, wherein the acid-labile active compound is 2-70% by weight of the oral solid active compound unit.

52. (New) The oral solid active compound unit as claimed in claim 50, wherein the acid-labile active compound is 5-40% by weight of the oral solid active compound unit.

53. (New) The oral solid active compound unit as claimed in claim 50, wherein the acid-labile active compound is 10-20% by weight of the oral solid active compound unit.

54. (New) The oral solid active compound unit as claimed in claim 11, wherein the fatty alcohol is 10-70% by weight of the oral solid active compound unit.

55. (New) The oral solid active compound unit as claimed in claim 54, wherein the fatty alcohol is 20-70% by weight of the oral solid active compound unit.

56. (New) The oral solid active compound unit as claimed in claim 54, wherein the fatty alcohol is 20-60% by weight of the oral solid active compound unit.

57. (New) The oral solid active compound unit as claimed in claim 54, wherein the fatty alcohol is 30-60% by weight of the oral solid active compound unit.

58. (New) The oral solid active compound unit as claimed in claim 11, wherein the solid paraffin is 10-70% by weight of the oral solid active compound unit.

59. (New) The oral solid active compound unit as claimed in claim 58, wherein the solid paraffin is 20-60% by weight of the oral solid active compound unit.

60. (New) The oral solid active compound unit as claimed in claim 58, wherein the solid paraffin is 30-60% by weight of the oral solid active compound unit.